|  | Application No.                             | Applicant(s)                 |
|--|---|------------------------------|
| Notice of Allowability   | 10/517,559                                  | ARRINGTON ET AL.             |
|  | Examiner                                    | Art Unit                     |
|  | Sun Jae Y. Loewe                            | 1626                         |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. |   |                              |
| 1. This communication is responsive to <u>amendment filed 10/22/2007 and interview summary dated</u> .   |   |                              |
| 2. The allowed claim(s) is/are 1-6,8,11-16 now renumbered as claims 1-13.  |   |                              |
| <ul> <li>3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some* c) None of the:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> </ul>  |   |                              |
| 3. Copies of the certified copies of the priority documents have been received in this national stage application from the   |   |                              |
| International Bureau (PCT Rule 17.2(a)).   |   |                              |
| * Certified copies not received:   |   |                              |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.   |   |                              |
| 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.   |   |                              |
| 5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.   |   |                              |
| (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached   |   |                              |
| 1) hereto or 2) to Paper No./Mail Date   |   |                              |
| (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of<br>Paper No./Mail Date  |   |                              |
| Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).  |   |                              |
| 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.  |   |                              |
|  |   |                              |
| Attachment(s)  1. Notice of References Cited (PTO-892)   | 5. Notice of Informal P                     | Patent Application           |
| 2. Notice of Draftperson's Patent Drawing Review (PTO-948)   | 6. ⊠ Interview Summary<br>Paper No./Mail Da |                              |
| 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date  | 7. 🛛 Examiner's Amendr                      |                              |
| Examiner's Comment Regarding Requirement for Deposit of Biological Material  | 8. 🛛 Examiner's Stateme                     | ent of Reasons for Allowance |
| o. Stological material   | 9.  |                              |
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### **DETAILED ACTION**

1. Claims 1-6, 8 and 11-16 are pending in the instant application and appear to be allowable. Claims 9 and 17-42 were cancelled by amendment filed on July 26, 2007. Claims 7 and 10 were cancelled by amendment filed on October 22, 2007.

### Examiner's Amendment

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Nicole Beeler on November 1, 2007.

This application has been amended as follows:

Claims 1-4: Replace

R1 is selected from:

(C<sub>1</sub>-C<sub>6</sub>-alkylene)<sub>n</sub>(C=X)NR<sup>c</sup>R<sup>c</sup>,
 said is optionally substituted with one or more substituents selected from R<sup>10</sup>; "

with

. .

R1 is selected from:

1) (C<sub>1</sub>-C<sub>6</sub>-alkylene)<sub>n</sub>(C=X)NR<sup>c</sup>R<sup>c</sup>', said alkylene is optionally substituted with one or more substituents selected from R<sup>10</sup>; "

Claims 1-6: Replace

R3, R4, R8, and R9 are independently selected from:

- 1) H, and
- 2) C1-C10 alkyl,

with

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R3, R4, R8, and R9 are independently selected from: i) H, and 2) C1-C10 alkyl. . For the first line of the definition of R<sup>c</sup> and R<sup>c</sup> delete "poperidine," Claims 1-6: For the second line of the definition of R<sup>c</sup> and R<sup>c'</sup> delete "oxotriazole." Claims 1-6: For the third line of the definition of R<sup>c</sup> and R<sup>c'</sup> delete "piperazine." Claims 1-6: For the third line of the definition of R<sup>c</sup> and R<sup>c'</sup> delete "dioxolane." Claims 1-6: For the eighth line of the definition of R<sup>c</sup> and R<sup>c</sup> delete "oxotriazole," Claims 1-2: For the ninth line of the definition of R<sup>c</sup> and R<sup>c'</sup> delete "dioxolane." Claims 1-2: Claims 5-6: Replace R1 is selected from: (C=O)NRCRC', " 1) with R1 is selected from: (C=O)NRCRC' . " 1) On page 34, insert the word "and" between the following two entries: Claim 11: 1-{3-[(25)-4-(2,5-difluorophenyl)-2-phenyl-2,5-dihydro-1H-pyrrol-1-yl]propanoyl}-4-(methylsulfonyl)pipcrazine;  $1-\{3-[(2S)-4-(2,5-difluor ophenyl)-2-phenyl-2,5-dihydro-1 \textit{H-pyrrol-1-yl}\} propanoyl\} piperidin-4-pyrrol-1-yl\} propanoyl\} piperidin-4-pyrrol-1-yl] propanoyl] pr$ ol; On page 35, insert the word "and" between the following two entries: Claim 12: 4-(5-chloro-2-fluorophenyl)-N,N-dimethyl-2-phenyl-2,5-dihydro-1H-pyrrole-1-carboxamide;

Claim 13: a) On page 35, insert the word "and" between the following two entries:

carboxamide;

(2S)-4-(2,5-difluorophenyl)-N-methyl-2-phenyl-N-piperidin-4-yl-2,5-dihydro-1H-pyrrole-1-

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(2S)-4-(2,5-difluorophenyl)-2-(3-hydroxyphenyl)-N,N-dimethyl-2,5-dihydro-1H-pyrrole-1-carboxamide;

(2S)-4-(2,5-difluorophenyl)-N-methyl-N-(1-methylpiperidin-4-yl)-2-phenyl-2,5-dihydro-1H-pymole-1-carboxamide; and

b) On page 35, replace "and" by "or" in the following entry:

(2S)-4-(2,5-difluorophenyl)-N-methyl-N-(1-methylpiperidin-4-yl)-2-phenyl-2,5-dihydro-1H-pyrrole-1-carboxamide; and

Claim 14: a) On page 35, replace:

" 14. (Previously amended) A compound which is: "

with

"14. (Previously amended) A compound selected from: "

- b) Insert a semicolon after each compound name
- c) On page 38, insert the word "and" between the following two entries:

1-{3-[(2S)-4-(2,5-difluorophenyl)-2-phenyl-2,5-dihydro-1*H*-pyrrol-1-yl]propanoyl}-4-(methylsulfonyl)piperazine

1-{3-[(25)-4-(2,5-difluorophenyl)-2-phenyl-2,5-dihydro-1H-pyrrol-1-yl]propanoyl}piperidin-4-ol

## Response to Amendment

3. The amendment and arguments filed on October 22, 2007 were fully considered. All grounds of rejection and objection were overcome by amendment and are therefore <u>withdrawn</u>. The double patenting rejection was withdrawn, pursuant MPEP 804.I.B, because this was the last remaining ground of rejection.

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# Reasons for Allowance

4. The following is an examiner's statement of reasons for allowance.

The closest structure in the prior art (eg. Winn et al., AN:1997:568105, RN: 178607-80-2) does not meet the structural limitations for the 2,5-dihydropyrrole core and variables  $R_4/R_5$  instantly claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sun Jae Y. Loewe whose telephone number is (571) 272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sun Jae Y. Loewe Art Unit 1626

HEBECCA ANDERSON PRIMARY EXAMINER